PD4 Exh 12

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DEA Compliance Procedure	No:
Subject: **Identification and Review of Peculiar Orders** **Controlled Substance Suspicious Order Monitoring Program**	Revision No.: **Draft 4 Published 07/15/08** Effective Date: Supersedes Date: **NEW** Page No.: **1 of 4**

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PURPOSE:

This procedure formally outlines the internal criteria and standards to identify, capture, investigate, report suspicious orders to the Drug Enforcement Administration (DEA) prior to shipment.

SCOPE:

Applies internally to Covidien Customer Service Group, Information Services Group, DEA Compliance, and Security for monitoring of controlled substance orders received electronically or manually, bulk or finished dosage products, for all active customer accounts from order placement to shipment.

REFERENCES:

- Title 21 CFR 1301.74(b)

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

OVERVIEW:

DEA cannot/will not tell a DEA registrant if an order is legitimate and/or if an order should be shipped. It is fundamental for sound operations that DEA registrants take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently identify those transactions that are suspicious in nature.

The Procedure for Identification and Review of Peculiar Orders, Suspicious Order Monitoring Program, is designed for compliance by developing systems to:

Identify, capture, and hold orders that meet Peculiar Order criteria

Investigate Peculiar Orders and release for shipment if authorized after review by Security and DEA Compliance

Elevate Peculiar Orders to the level of Suspicious Order based upon investigation results and notify DEA [per CFR21 1301.74(b)].

DEFINITIONS:

Peculiar Order	A controlled substance order that meets an internal, established criteria that will be placed on hold pending further review by DEA Compliance.
Suspicious Order	A Peculiar Order that has been reviewed by DEA Compliance and Security and has been elevated to DEA reporting status.

REPORTS REQUIRED

- Do Not Ship List

RESPONSIBILITIES:

Customer Service Representative

Perform the following activities for each controlled substance order:

1. Verify that the account is in good standing
   a. Reference the "Do Not Ship List" file on the Shared Drive.
2. Assure that the order is valid
   a. Verify that the customer has provided a complete order
3. Check customer DEA registration status
   a. Current customer DEA registration certificate is to be on file in Customer Service department
   b. DEA registration suspension/revocations can be checked by calling DEA Compliance group who will refer to DEA webpage, Registration Validation Link
4. For CI and CII controlled substance orders
   a. Verify customer has provided a DEA 222 form
   b. Obtain a "Certificate of Available Procurement Quota" from customers using a Manufacturing registration DEA 222 Form
   c. Obtain a "Statement of Intended Use" from customers using a Research, Compounding Pharmacy, or Analytical Lab registration DEA 222 Form
      I. Forward the "Statement of Intended Use" to DEA Compliance
5. Review the order based on the criteria above and identify order as "Peculiar" if there are any exceptions
6. Forward "Peculiar" order information to Customer Service Manager and Security Director

Customer Service Manager

1. Review the IS system generated Peculiar Order Report which lists orders that meet the criteria established in this procedure
   a. Annotate the report with applicable explanation that authorizes shipment of Peculiar Orders that deviates from normal order pattern, size, frequency such as trade show sales, etc.
   b. Manually release orders in the order entry system that are authorized to ship
   c.. For orders that have no applicable explanation for deviation from normal order pattern, size, frequency, the order will remain on hold pending further investigation by the business group and Security/DEA Compliance.
   d.. Upon completion of review, forward the annotated Peculiar Order Report to Security/DEA Compliance for record retention per Company policy
2. Maintains the Do Not Ship List on the Shared drive by updating for any customer for which shipment has been cancelled based on suspicious order criteria.

Information Service Department

1. Programs and publishes the order entry generated Peculiar Order Report which lists orders that meet the criteria as follows:
   a. Orders in excess of [redacted] the amount of product ordered during the previous [redacted] average by customer, by sku.
   b. Orders that appear on the Peculiar Order Report will be placed on hold automatically within the order entry system
   c. The Peculiar Order Report exempts orders from the 20? largest customers in each customer category (Wholesalers, Distributors).

Security Director and DEA Compliance

1. Investigates Peculiar Orders that have no applicable explanation for deviation from normal order pattern, size, frequency
2. Consults with the business group as part of the Peculiar Order investigation
3. Reviews Peculiar Orders for correlation to DEA webpage "Drugs of Concern Listing"
4. Responsible for DEA reporting of orders that have been escalated from Peculiar Order status to Suspicious Order status

5. Maintains files of Peculiar Order Reports and Suspicious Order Investigation documentation per Mallinckrodt/Covidien per Covidien Record Retention Policy

6. Responsible for training internal customers on this procedure.